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HESLIN ROTHENBERG FARLEY & MESITI P.C.
5 COLUMBIA CIRCLE
ALBANY, NY 12203-5160

EXAMINER
FORD, JOHN K

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/881,909	Applicant(s) Wisniewski et al.
	Examiner FORD	Art Unit 3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) 1-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) 1-55 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☑ Claims 1-55 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☑ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

Extremely relevant prior art is discussed in the specification under the heading "2. Description of the Prior Art". (page 1, line 22 – page 2, line 17). Unfortunately the description is somewhat ambiguous. Carefully drawn sketches of this prior art (if no publication exists) are required in response to this action showing this prior art with enough detail so as to permit meaningful comparison to what is claimed here in claims 1-55. Failure to provide full disclosure of this prior art will result in a holding of non-responsiveness. This is not the first time the Examiner has requested additional disclosure of this prior art in this series of applications. NO additional disclosure has thus far been provided and it is deemed long overdue.

Applicant is put on notice that, in the apparatus as claimed, patentability can not be predicted on the material intended to be processed in the container. The apparatus simply does not undergo a metamorphosis into a new apparatus simply by placing a biopharmaceutical product into it.

It is respectfully submitted that the patentability of an apparatus cannot be predicated on a new use of what is otherwise an old apparatus. This is very old case law. See Brown v. Piper 91 U.S. 37, 23 LED. 200 (1875), and Roberts v. Ryer 91 U.S. 150, 23LED 267 (1875). See In re Thuau 57 USPQ 324 (CCPA 1943) for the leading new case and Ex Parte Masham 2 USPQ2d 1647 (BPAI 1987).

This application contains claims directed to the following patentably distinct species of the claimed invention: First species of Fig. 1 and 2,

Second species of Fig. 4,

Third species of Fig. 5,

Fourth species of Fig. 6,

Fifth species of Fig. 7,

Sixth species of Fig. 8,

Seventh species of Fig. 9, (more than one, maybe),

Eighth species of Fig. 10,

Ninth species of Fig. 11 and 12,

Tenth species of Fig. 13,

Eleventh species of Fig. 14 and

Twelveth species of Fig. 15 and an in-determinant number of additional species illustrated in Fig. 16-19.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim appears to be generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

In the event applicants elect any figure which has numbers variants associated with it, a particular variant must be enumerated to comply with this requirement.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-10, 12-34, 36-37 and 39-55 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over the 1992 Wisniewski and Wu article or the 1986 Kalhozi and Ramadhyani article Studes on heat transfer....embedded in a solid phase medium (reference 29 on page 140 of the 1992 article by Wisniewski and Wu).

As stated above, claims drawn to an apparatus, cannot predicate patentability on the material intended to be worked upon. Moreover, with regard to the recitation "thermal transfer bridge" the Examiner relies on the expansive definition given to this term in the specification on page 4, line 3 through page 5, line 16.

Claims 1-5, 7-10, 12-34, 36-37 and 39-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of the 1992 publication by Wisniewski and Wu and the 1986 Kalhozi and Ramadhyani article entitled "Studies on heat transfer from a vertical cylinder with or without fins, embedded in a solid phase change medium" (reference 29 on page 140 of the 1992 article by Wisniewski and Wu).

The 1992 Wisniewski and Wu research paper appears to disclose every feature of the claimed invention including heat exchange member (i.e. fins) in close spaced proximity to the interior surface of the container. It lacks a "spurtube" type cooler in the center. See Figure 1 and the description thereof found on pages 134 and 136. Note page 135 should follow page 136 and was apparently printed out of order. The Examiner did not catch this error when he examined SN 08/895,782.

There is not explicit disclosure of any thermal ice bridge in the 1992 Wisniewski and Wu research paper (if that what is being claimed in the phrase "thermal transfer

bridge", however see specification, page 5, lines 10-13, for apparently inconsistent definition: when the medium is being heated, after being frozen, the ice in the "gap" claimed between the tips of the fins and the wall of the container melts quickest leaving liquid in the "gap", hence it would appear that "thermal transfer bridge" is much broader term than simply an ice bridge) formed between the tips of these fins and the interior wall of the container and no explicit disclosure of how close to the container wall these heat transfer fins extend, although they must extend far enough to define "compartments" between the fins (1992 Wisniewski and WU research paper, page 136, first full paragraph).

The thermal bridge of ice will inherently form between the tip of the heat transfer fins and the interior of the container because they are the closest points to one another and both are actively cooled by circulating cooled silicon oil. Closely spaces cooled surfaces are known by those of skill in the refrigeration art to form ice bridges when a liquid is being frozen into a solid.

As evidence to support the Examiner's statement the closely spaced cooled surfaces will inherently form ice bridges (see MPEP 2112-2112.02, dealing with inherency, incorporated here by reference), the reader is referred to Voorhees USP 983,466 page 1, col. 2, line 97 – page 2, col. 1, line 5 (Voorhees is not relied upon explicitly here, see MPEP 2131.01, sub-section III), wherein it states:

"Whether ice forms in single cakes about several freezing elements or forms in a single cake enclosing a plurality of such elements depends upon the spacing of the several freezing elements from each other. In the first instance of course, ice forms

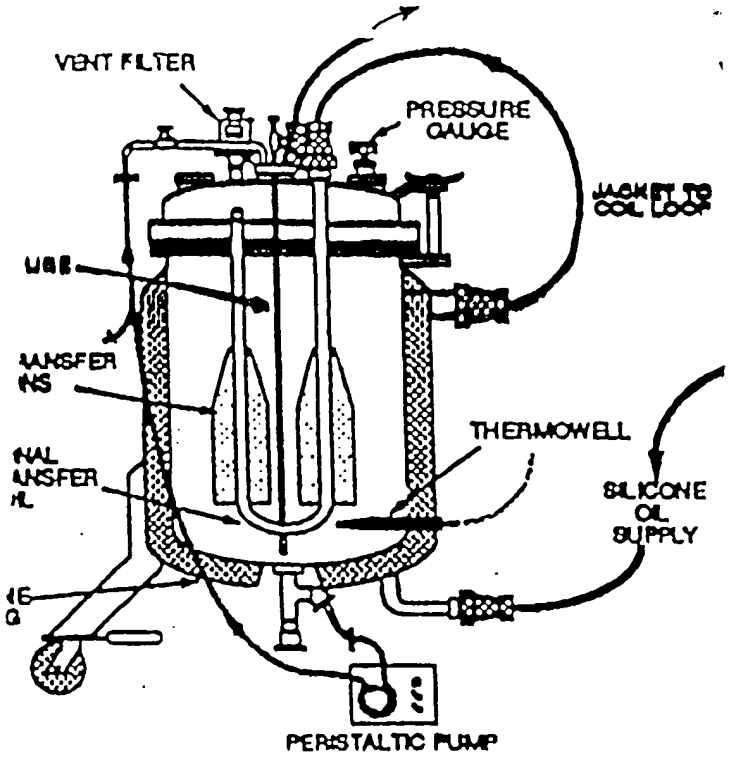
separately about each freezing element, but if these elements be ***close together*** the ice surrounding these element will ***coalesce into a single cake***; and after this has occurred freezing will go on from the surface of the combination cake so formed.: (Emphasis supplied).

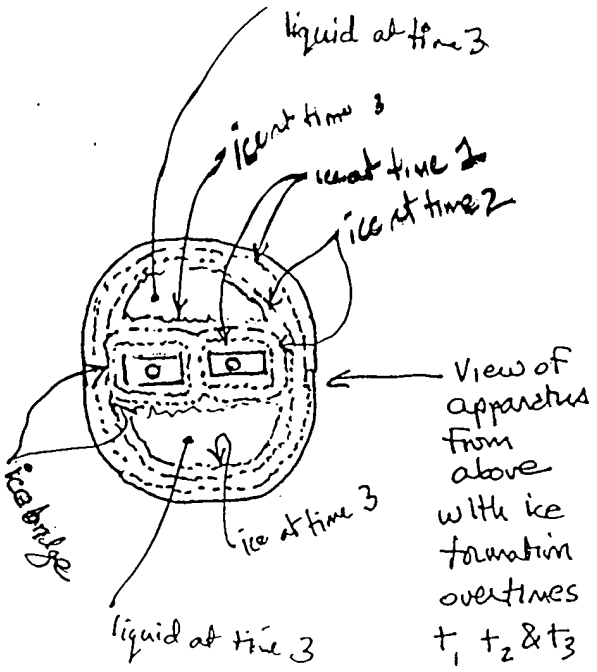
Furthermore, Voorhees, page 2, col. 1, lines 14-21 states:

"I have shown a number of other elements so spaced relatively as to from a single cake 15 of length comparable to cakes formed in plate processes. Of course if the ***freez-ing were continued indefinitely the cakes 12, 13, 14 and 15 would ventually coalesce and freeze to the sides of the tank..."***

It is evident that ice will build upon the heat exchanger and walls of the vessel shown in Figure 1 of 1992 Wisniewski and Wu research paper, during the freezing phase, until they bridge as shown in the diagrams below, a fact that can be established by basic scientific principles. Burroughs et al. USP 3, 318,105 illustrates the phenomena. As is clearly seen in Figs. 1A-1C ice builds up evenly cooled surfaces and even as the top surface freezes the ice coating on the submerged surfaces continues to build up more or less evenly. The same type of analysis is disclosed by Finnegan USP 2,129,572, illustrating that the time required to freeze a substance varies "approximately as the square of the thickness of such substance" with slower freezing generally leading to undesirable concentration effects (what applicants and the 1992 Wisniewski and Wu research paper refer to as "cryoconcentration"). Finnegan, like the 1992 Wisniewski and Wu research paper, discloses the use of heat exchange fins (projecting inwardly from the exterior wall of the container in the case of Finnegan) to form compartments

within the tank to speed the freezing process. Finnegan illustrates using a series of dotted lines how the freezing process progresses over time in various geometries of heat exchange fins. Applying this same science (illustrated by Burroughs and Finnegan) to the system disclosed by 1992 Wisniewski and Wu research paper yield the results illustrated on the next page for the system disclosed by the 1992 Wisniewski and Wu research paper in Figure 1.





Even if the 1992 Wisniewski and Wu research paper is deemed not to disclose heat exchanger fins "in close spaced proximity" to the container wall, to have extended the fins in Figure 1 of the 1992 Wisniewski and Wu publication to a point "in close spaced proximity" to the interior surface to the container in order to advantageously

increase the rate of heat transfer and "divide the tank volume into compartments to decrease the freezing the thawing time and to reduce cryoconcentration effects" (1992 publication, page 136, col. 1, first full paragraph) would have been obvious to one or ordinary skill in the art.

The examiner submits that the fins shown in Figure 1 of the 1992 Wisniewski and Wu publication are already in spaced proximity to the interior wall of the container such that substantially discrete compartments are formed (see page 136, col. 1, first full paragraph) an effect that would be enhanced if the fins were further extended to a point closer to the interior wall of the container.

Moreover, larger fins would increase the amount of surface area for heat transfer, giving an added advantage. On page 136 of the 1992 Wisniewski and Wu publication it states that the "fin's length, thickness and shape were designed to maintain ***efficient heat transfer*** during freezing and thawing." (Emphasis supplied). It is not open to any serious debate that larger, thicker, fins that extend to points closer to the interior wall of the container are more efficient heat transfer vehicles than smaller, thinner fins that do not extend to points closer to the interior wall of the container.

The 1992 Wisniewski and Wu publication states on page 136: "The heat transfer fins were configured to ***divide the tank into compartments*** to decrease the freezing and thawing time and to reduce cryoconcentration effects. ***Compartmentation*** of the tank is especially effective for maintaining liquid in a static state to minimize cryoconcentration." (Emphasis supplied). The fins are designed to maintain "efficient heat transfer during freezing and thawing" (page 134, col. 2, 1992 Wisniewski and Wu

publication). Figure 1 (page 134) of the 1992 Wisniewski and Wu publication clearly shows heat transfer fins extending outwardly for the internal heat transfer coil towards the interior wall of the container. Extending the fins further outwardly to aid in the formation of compartments to minimize cryoconcentration would have been another motivation to one of ordinary skill in the art to make the same modification.

The 1986 Kalhori and Ramadhyani article entitled "Studies on heat transfer from a vertical cylinder, with or without fins, embedded in solid phase change medium" (reference 29, on page 140 of the 1992 article by Wisniewski and Wu), like applicants have disclosed in Figures 1 & 2 of their drawings, shows in Figure 3 a "spur-tube" type heat exchanger with six heat transfer fins welded to it in a manner almost identical to what applicants show in Figures 1 and 2 of the current application. The finned heat exchanger as shown is immersed in a container of paraffin and the melting and freezing processes were studied in great detail with a material, paraffin, of known characteristics. See the abstract of this article on the first page. Again, fins that span nearly the entire interior of the container were found to be especially effective, with a host of definitive technical data presented (that is unnecessary to discuss here) showing the virtues of these large fins in improving heat exchange. See last sentence of article- "In view of the ***superior heat transfer characteristics, the finned cylinder*** is a much better choice of the design of a practical thermal storage unit." (Emphasis supplied).

In view of each of the above teachings, it would have been obvious to one of ordinary skill in the art to have extended the fins of the prior art disclosed in the 1992 article by Wisniewski and WU to substantially the inner periphery of the container,

leaving a small gap to permit the heat exchanger to be removed for cleaning (as is disclosed to be necessary in the 1992 article by Wisniewski and Wu page 136). Extending the fins to substantially the inner periphery of the container would:

a. Improve heat transfer by increasing heat transfer surface area and

b. Improve "comparmentation" by forming ice bridges.

In addition, to have replaced the centrally mounted heat exchanger and fins of the 1992 article by Wisniewski and Wu disclosed in Figure 1 with the heat exchanger and fins shown by Kalhori and Ramadhyani in Figure 3 to improve heat transfer and to facilitate ease of construction as well as to facilitate easy removal form the frozen mass would have been obvious to one of ordinary skill in the art.

Claims 1-5, 7-10, 12-34, 36-37 and 39-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over the 1992 publication by Wisniewski and Wu and/or 1986 Kalhori and Ramadhyani article as applied to claims 1-5, 7-10, 12-34, 36-37 and 39-56 above, and further in view of: Euwema (USP 3,550,393), Cothern et al (USPN 5,535,598), West (USPN 2,114,642), Morrison (USPN 1,874,578) and Nakao (JP 57-58087).

Euwema discloses ice bridges forming at the ends of vanes 36 and 38 when wall 10 is cooled by a refrigerant. See column 3, lines 4-19. The ice is shown at 18 (Figure 1) and rapidly bridges the gap between the tips of vanes 36 and 38 and the cooled surface 10 of the refrigeration device (Figure 2) in much the same manner that applicants disclose in their specification with regard to ice forming in the gap between the tips of their fins 8 and the inner wall of their container. Euwema's ice divides the

regions on either side of vanes 36 and 38 into separate compartments to facilitate improved heat exchange with the liquid in those compartments. In other words, the ice bridges in Euwema prevent the fluids in the compartments on either side of vanes 36 and 38 from intermixing in much the same manner that the 1992 publication by Wisniewski and Wu discusses is a desirable feature in their invention (see the 1992 publication by Wisniewski and Wu, page 136, first full paragraph – "The heat transfer fins were configured to divide the tank volume into compartments to decrease the freezing and thawing time and to reduce cryoconcentration effects").

Likewise, Cothern et al teaches (Figures 1-3) a jacketed tank (Figure 2) similar to applicants and a fin-like heat exchanger formed with plates that divide the interior of the tank into a number of compartments by spanning nearly the entire tank to areas very close (close spaced gaps) to the sidewalls of the tank (in much the same manner applicants disclose, albeit in a square tank as opposed to a round tank). These large heat exchanger plates provide great surface area for improved freezing as discussed by Cothern in column 7, lines 46-52. In Cothern, having these closely spaced gaps between the distal ends of the immersed heat exchanger and the walls of the jacketed tank permits the heat exchanger to be withdrawn easily for cleaning and reduces the need for tight manufacturing tolerances in the immersed heat exchanger fit tightly into the tank and form fully non-communicating compartments.

West in Figures 5 and 6 illustrates a fast freezing system which freezes the substance so fast that there are no cryoconcentration effects. See page 2, lines 60-66 and lines 70-72. The periphery of the heat exchanger structure 15 is clearly spaced

form the container 8. In Figure 6 the freezing is applied to both the inside and outside of the container to further reduce cryoconcentration effects. See page 2, the last three paragraphs of the specification.

Morrison also teaches that fins 7 spanning nearly the entire interior of a container (which container is believed to be shown in phantom lines in Figure 1) "insure maximum heating or cooling surface, so that operation of the device may be carried out with facility" (Morrison, column 1, lines 8-13).

Finally, Nakao teaches metallic fins 5 spanning nearly the entire interior of a container having a phase-change material therein. A relatively small gap exists between the end of these fins and the wall of the container. These fins greatly aid in the transfer of heat introduced at, and removed from, the periphery of the container.

In view of each of the above teachings, it would have been obvious to one of ordinary skill in the art to have extended the fins of the prior art disclosed in the 1992 article by Wisniewski and Wu to substantially the inner periphery of the container, leaving a small gap to permit the heat exchanger to be removed fro cleaning (as is disclosed to be necessary in the 1992 article by Wisniewski and Wu page 136). Extending the fins to substantially inner periphery of the container would:

a. Improve heat transfer by increasing heat transfer surface area as taught by Cothern, West, Morrison, Nakao,

b. Improve "compartmentation" by forming ice bridges as explicitly taught by Euwema and

c. Eliminate cryoconcentration effects as taught by West.

In addition, to have replaced the centrally mounted heat exchanger and fins of the 1992 article by Wisniewski and Wu disclosed in Figure 1 with the heat exchanger and fins shown by Kalhori and Ramadhyani in Figure 3 to improve heat transfer and to facilitate ease of construction as well as to facilitate easy removal form the frozen mass would have been obvious to one of ordinary skill in the art.

Cothern in column 7, line 54 – column 8, line 8 teaches various controls for controlling both rate and cooling direction in a freeze container by varying refrigerant flow in the various portion of the device. To the extent that they system disclosed by applications can accomplish the functions set forth in the claims it would have been obvious to have configured the 1992 Wisniewski and Wu prior art with suitable controls to achieve the same end (those controls being broadly taught by Cothern). Since applicants' own specification is virtually devoid of how these functions are accomplished it must be surmised that obtaining these results must be within the skill of those skilled in the refrigeration art.

Claims 1-5, 7-10, 12-34, 36-37 and 39-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the prior art as applied to claims 1-5, 7-10, 12-34, 36-37 and 39-56 above, and further in view of the conceded prior art discussed on pages 1, line 22 – page 2, line 17 of the specification.

For the sake of completeness, even though the Examiner is unsure of the precise nature of applicant's admitted prior art, it appears that placing a heat exchanger structure with fins on it into a conditioned container is known however in this prior art the

fins are attached to both the wall of the container and the heat exchange structure making routine removal of the finned heat exchange structure impossible. Such a deficiency however does not seem to be precluded by most of the claims and even as to those which do claim non-attachment of the heat exchange structure to the tank wall, such a fairly taught by the 1992 Wisniewski and Wu article.

Claims 11 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the prior art as applied to claim1 and 30 above, and further in view of Brown or Gross.

Brown (Fig 2) and Gross (Fig 24) each teach means forming spiral paths on the outside of a tank. To have configured the 1992 Wisniewski and Wu prior art with a spiral path on the outside of the tank would have been obvious to improve heat exchange.

Claims 6 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of the prior art as applied to claims 1 or 30 above, and further in view of Nagashio or Koerber.

Nagashio and Koerber disclose removable liners for large tanks particularly for cleaning and leakage prevention. To have used such liners in the tanks disclosed in the prior art advantageously permit fast cleaning an low leakage would have been obvious.

Any inquiry concerning this communication should be directed to John Ford at telephone number 703-308-2636.

John K. Ford
Primary Examiner

typed 1/28/03 11:57